

REMARKS

This paper and the accompanying Request for Continued Examination are responsive to an Official Action in this case that issued on January 8, 2008. In that Action, the Examiner finally rejected pending claims 1-40.

Responsive to the Action, and for the purposes of more particularly pointing out and distinctly claiming the subject matter that applicant regards as it's invention, claims 1, 4-7, 13, 14, 18, 19, 25, 28, and 33-35 have been amended. Furthermore, claims 2-3, 8-12, 20, 26, 27, and 29-32 have been canceled.

Reconsideration is respectfully requested in view of the foregoing amendments and the following comments.

Claim Rejections under 35 USC §102

The Office rejected claims 1, 2, 25, 27, 28, 35, and 38-40 under Section 102 as being anticipated by U.S. Pat. No. 6, 654,000 to Rosenberg.

Amended claim 1 recites an apparatus comprising:

pseudo skin;
a receiver, wherein said receiver receives an end effector through an insertion region in said pseudo skin; and
a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein:
(a) said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin; and
(b) said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.

Rosenberg does not disclose what is recited in amended claim 1. In particular, and among any other distinctions, Rosenberg does not disclose "a first device for performing a first skin-interaction technique ... selected from the group consisting of palpation and occlusion."

As a consequence, amended claim 1 is allowable over Rosenberg. Claims 4-7, 13-19, and 21-24 are allowable based on their dependence on claim 1.

The recitation of additional patentable features in the dependent claims provides a secondary basis for patentability. For example, claim 4 recites:

The apparatus of claim 1 further comprising a second device for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin.

Rosenberg does not disclose that “a second device for performing a second skin-interaction technique on the pseudo skin” is disposed beneath and covered by pseudo skin.

Claim 5 recites:

The apparatus of claim 4 wherein:
said second skin-interaction technique comprises skin stretching; and
said second skin-interaction region of said pseudo skin is closer to a user than said insertion region of said pseudo skin when said user is using said apparatus.

As previously noted, Rosenberg does not disclose a “second skin-interaction technique,” so, clearly, there is no disclosure that this technique should be a “skin stretching” nor is there any disclosure that the region where the skin-stretch technique takes place is closer to a user than the region where the end effector is inserted.

Claim 5, and a number of other claims discussed below, pertain to various features of the claimed apparatus that are intended to improve its utility as a simulation tool. In particular, these claims pertain to features that enable the apparatus to emulate what a practitioner would experience if the vascular access procedure were being performed on an actual patient, rather than an inanimate simulator.

For example, the apparatus recited in claim 5 is configured so that, with respect to a practitioner that is performing the simulation, the location at which the needle/catheter is inserted through the (pseudo) skin and the location at which the practitioner would stretch the skin to facilitate the insertion are correct.

Amended claim 25 recites an apparatus comprising:

a housing, wherein said housing has an opening in an uppermost surface thereof;
pseudo skin, wherein said pseudo skin covers said opening;
an end effector, wherein said end effector is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure; and
a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin, and wherein said plurality of mechanisms include:
(a) a first mechanism is for simulating a skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin; and
(b) a second mechanism for receiving said end effector.

Rosenberg does not disclose what is recited in amended claim 25. Namely, and among other features, Rosenberg does not disclose:

- (a) a housing having an opening in an uppermost surface thereof;
- (b) a plurality of mechanisms ... contained completely within the housing;
- (c) a first mechanism for simulating a skin-stretch technique.

As a consequence, the Section 102 rejection of claim 25 over Rosenberg should be withdrawn. Likewise, the Section 102 rejections of claims 28, 33, and 34, which are dependent on claim 25, should be withdrawn as well. Furthermore, the recitation of additional patentable features in these dependent claims provides a secondary basis for their patentability.

Amended claim 35 recites an apparatus comprising:

a pseudo skin;
a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure, including at least one mechanism for performing a skin-interaction technique that is performed on said pseudo skin, wherein said plurality of mechanisms are disposed under said pseudo skin and are covered by said pseudo skin; and
a housing, wherein said housing contains said plurality of mechanisms.

Rosenberg does not disclose what is recited in claim 35. In particular, Rosenberg does not disclose a “plurality of mechanisms with which a user interacts for simulation a vascular-access procedure, including at least one mechanism for performing a skin-interaction technique that is performed on the pseudo skin.”

Since Rosenberg does not disclose what is recited in amended claim 35, the Section 102 rejection of amended claim 35 over Rosenberg should be withdrawn. The Section 102 rejections of claims 38-40, which are dependent on claim 35, should be withdrawn as well.

Claim Rejections under 35 USC §103

The Office rejected claims 3-24 and 26 under Section 103 as being obvious over Rosenberg in view of U.S. Pub. Pat. App. 2003/0031993 to Pugh.

Claims 3, 8-12, 20, and 26 have been canceled. Some of the limitations of claim 3 have, however, been incorporated into claim 1. All claims that are now pending in this case that are rejected over Section 103 are dependent on claim 1. We therefore turn now to claim 1 and show that it is not obvious over the combination of Rosenberg and Pugh.

Amended claim 1 recites an apparatus comprising:

<p>pseudo skin; a receiver, wherein said receiver receives an end effector through an insertion region in said pseudo skin; and a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein: (a) said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin; and (b) said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.</p>

Neither Rosenberg, Pugh, nor the combination thereof disclose or suggest what is recited in claim 1. Namely, there is no disclosure in either Rosenberg or Pugh of a “first device for performing a first skin-interaction technique that is used in conjunction with a vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of

consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin.”

The skin interaction techniques that are used in conjunction with a vascular access procedure are very specific. These techniques include: (1) palpation, (2) occlusion, and (3) skin stretch. As disclosed in U.S. Pat. Appl. 10/807,017, which is incorporated by reference into the present case:

[0007] Palpation is a multi-purpose technique. It can be used by a practitioner to locate hidden veins. Veins might not be readily locatable due to the advanced age or poor physical condition of the patient, the procedure being performed, or due to other reasons. To palpate for hidden veins, the practitioner pats the skin. Palpation can also be used to obtain information about a candidate vein once it has been located. In particular, the practitioner can determine whether the candidate vein is sufficiently engorged. A practitioner can also determine, via palpation, whether a vein is sufficiently straight (at an intended insertion point) for catheterization. To palpate a vein to obtain this type of information, the practitioner moves one or two fingers lightly over the candidate vein.

[0008] Occlusion is a technique that is performed during catheterization. Specifically, a finger or thumb of the non-dominant hand is used to apply pressure on the catheter at the insertion point so that no blood leaks out of the hub of the catheter when the stylet is removed. To practice the third technique mentioned above—the skin-stretch technique—the thumb of the non-dominant hand pulls a patient’s skin, rendering it taut. This reduces a patient’s level of discomfort and anchors the vein so that it doesn’t move during angiocatheter insertion.

Rosenberg doesn’t disclose any palpation or occlusion techniques. To the extent that Pugh discloses “palpation techniques” for checking organs, which can be performed on the organ surface (*i.e.*, within the body) or on the skin, such techniques are different than the palpation techniques that are used “in conjunction with a simulated vascular-access procedure,” such as to palpate for hidden veins or to determine if a vein is sufficiently straight for catheterization.

As a consequence, claim 1 is not obvious over the combination of Rosenberg and Pugh. Since claims 4-7, 13-19, and 21-24 are ultimately dependent on claim 1, they are not obvious over the combination of these references either.

Conclusion

It is believed that claims 1, 4-7, 13-19, 21-25, 28, and 33-40 now presented for examination are in condition for allowance. A notice to that effect is solicited.

Respectfully,
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